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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,492

12/04/2001

Rango Dietrich

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34375 7590 06/24/2008

NATH & ASSOCIATES PLLC  
112 South West Street  
Alexandria, VA 22314

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,492	<b>Applicant(s)</b> DIETRICH ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response after Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks and request for extension of time (2 months-granted), all filed 03/06/08 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment to the claims and/or persuasive remarks: (1) The 35 U.S.C. 112 1<sup>st</sup> paragraph, New Matter Rejection has been withdrawn; (2) The 35 U.S.C. §112, first paragraph rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 based on the term " acid labile active compounds" has been withdrawn.

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 are pending in this action. Claims 11, 18 and 33-36 have been amended. New claims 61-62 have been added. Claims 1-10, 12, 15-17, 21-32, 42, 43, 45-49, 56 and 59 have previously been cancelled. Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 remain rejected.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific fatty

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alcohols disclosed on page 5 of the specification, does not reasonably provide enablement for the generic “fatty alcohol”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the specific fatty alcohols disclosed on page 5, ¶ 5 of the specification. Namely, Applicants are only enabled for a fatty alcohol that is a linear, saturated or unsaturated primary alcohol having 10-30 carbon atoms. Applicants are non-enabled for all fatty alcohols. The definition of fatty alcohols as presented in the specification (page 5, ¶ 5) should be incorporated into all generic claims.

\* \* \* \* \*

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the examples at pages 14-17, which require the inclusion of a stearylamine and a polymer in addition to the fatty alcohol, does not reasonably provide enablement for the generic “fatty alcohol” *without* inclusion of the stearylamine and polymer. The specification examples demonstrate that the stearylamine and polymer (i.e., povidone) are required to form the active compound units. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the combination of a fatty alcohol, stearylamine and polymer. The examples demonstrate that the excipients refer to the stearylamine and polymer. The claims must include the presence of stearylamine and polymer, in addition to the fatty alcohol claimed, as this would be enabling. Applicant’s claims should be amended to reflect incorporation of all

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three components of a fatty alcohol, stearylamine and polymer in order to render the claims enabling.

***Response to Arguments***

Applicant's arguments filed 03/06/08 have been fully considered and were found to be partially persuasive.

▪ **35 U.S.C. 112 1<sup>st</sup> paragraph, New Matter Rejection:**

Applicant argued, "Applicants submit the skilled artisan would understand the teaching of the specification as including the limitation that the microsphere does not comprise an enteric coating."

Applicant's arguments have been considered and were persuasive. Accordingly, the 35 U.S.C. 112 1<sup>st</sup> paragraph, New Matter Rejection has been withdrawn.

▪ **35 U.S.C. §112, first paragraph rejection:**

Applicant argued, "Claims 11 and 18 have been amended to recite that the acid-labile active compound is substituted pyridin-2-yl-methylsulfinyl- 1H-benzimidazoles, substituted phenylmethylsulfinyl-1H-benzimidazoles, substituted cycloheptapyridin-9-ylsulfinyl-1H-benzimidazoles, and substituted pyridin-2-ylmethylsulfinylthienoimidazoles and may be present as a chiral compound, a pure enantiomer, or a mixture thereof in any mixing ratio, or in the form of its salt with a base, or in the form of a hydrate of its salt with a base."

Applicant's arguments were found persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 has been withdrawn.

Applicant argued, "With regard to (1) the phrase fatty alcohol, Applicants note that the several examples set forth in the present specification at page 5, paragraph 5 are more than sufficient to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. With regard to (3), Applicants submit that Examples 11-13, at page 15, of the specification clearly disclose preparations having only solid paraffin and fatty alcohol."

With regards to the 35 U.S.C. §112, first paragraph rejection of (1) and (3), Applicant's remarks have been considered but were not persuasive. The issue here is the scope of enablement and not enablement as argued in the response. The Examiner agrees that the invention is enabled. However one of ordinary skill in this art would appreciate the scope of enablement as being a required presence of stearylamine and polymer as exemplified and taught by examples 1-5 of the original specification. Admittedly when ingredients other than fatty alcohols are used, the additional examples evidence that stearylamine and a polymer would not be necessary.

The rejections of record have been maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

*hns*

June 19, 2008



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